

GAMMA HEALTHCARE, INC.,
Plaintiff,

v.

ALEX AZAR, in his official capacity
official capacity as Secretary, United
States Department of Health and
Human Services,

SEEMA VERMA, in her official
capacity as Acting Administrator for the
Center of Medicare and Medicaid Services,
AND

JEFF KAHRS, Deputy Regional Administrator
for (Region 7) the Center for Medicare
and Medicaid Services.

Defendants.

NOW COMES, Plaintiff, GAMMA HEALTHCARE, INC., by and through its attorneys,
Polsinelli PC, and complains as follows:

NATURE OF THE ACTION

1. This is a civil action for emergency injunctive relief, both preliminary and permanent, to prevent Defendants from improperly suspending Gamma Healthcare, Inc.'s certificates to operate clinical laboratories pursuant to the Clinical Laboratory Improvement Amendment of 1988 (“**CLIA**”) at its Poplar Bluff and Springfield laboratories thereby prohibiting GHC from providing laboratory services to long-term care facilities and other healthcare providers in Missouri and surrounding states.

2. On October 21, 2020, the Centers for Medicare and Medicaid Services (“**CMS**”) notified Gamma Healthcare, Inc. (“**GHC**”) that, because of surveys conducted at the laboratories by the Missouri Department of Health and Senior Services (“**MDHSS**”), it will suspend GHC’s CLIA certificates at its Poplar Bluff and Springfield laboratories effective October 26, 2020 (the “**October 21 Notices**”). The suspension will force GHC to cease all laboratory operations and will render GHC ineligible to receive payment for laboratory services provided to any patient who is covered by Medicare, Medicaid and/or private insurance.

3. Importantly, following the surveys, CMS gave GHC until October 26 to submit Allegations of Compliance demonstrating that it returned to substantial compliance with all requirements. Thus, CMS has demonstrated that it does not intend to review GHC’s allegations of compliance as the suspension date is the same day the Allegations of Compliance are due.

4. GHC implemented substantial and systemic corrective actions to address the alleged non-compliance and provided proof of such corrections to CMS, but CMS nonetheless has refused to accept multiple submissions of information and materials GHC prepared to demonstrate its corrective actions, its substantial compliance with all regulatory requirements and its proof that there has been no patient harm. GHC believes these corrective actions have returned the laboratories to substantial compliance with all regulatory requirements.

5. GHC has also filed administrative appeals to contest the October 21 Notices. Even though GHC has also filed a motion for expedited hearing, no hearing date has been set and GHC likely cannot proceed to hearing until after the suspension becomes effective.

6. CMS’s attempt to suspend GHC’s CLIA certificates violates GHC’s right to equal protection and due process of law under the Fourteenth Amendment to the United States Constitution.

7. If CMS suspends GHC's CLIA certificate on October 26, 2020, irreparable harm to both GHC, its clients, its patients, its employees and the Community will follow. CMS's improper sanctions will render GHC unable to perform any laboratory activities and render GHC ineligible to receive payment for laboratory services provided to any patient who is covered by Medicare, Medicaid and/or private insurance. Immediately upon suspension, GHC will be forced to stop performing laboratory services for all of its patients (at 2,500 long-term care facilities in 11 states), which immediately prevents thousands of long-term care residents from having access to the laboratory services that GHC provides, including the critical COVID-19 testing services that GHC had been providing to skilled nursing facilities and can continue to provide if able to continue operations. Given the short notice before suspension becomes effective, none of GHC's facility clients will be able to find a viable alternative laboratory service provider on short notice and therefore, will be without crucial laboratory services for a period of time.

8. GHC has no adequate remedy at law and seeks only to ensure compliance with its Due Process rights to preserve the status quo as it pursues its administrative remedies.

STATEMENT OF FACTS

A. PARTIES

9. Plaintiff, Gamma Health Care, Inc. ("**GHC**") operates a clinical laboratory that provides laboratory services in Poplar Bluff and Springfield, Missouri. The Poplar Bluff laboratory operates under CLIA Certificate #26D2102945 and the Springfield laboratory operates under CLIA Certificate #26D1041510.

10. Defendant, Alex Azar, sued in his official capacity only, is the Secretary of the United States Department of Health and Human Services ("**HHS**"), an agency of the United States government. As Secretary of HHS ("**Secretary**"), he is responsible for administering the Social

Security Act, 42 U.S.C. §§ 301, *et seq.*, and in particular for oversight of the Public Health Service Act, 42 U.S.C. §§ 263a, *et seq.*, and the Clinical Laboratory Improvement Amendments of 1988, 42 C.F.R. §§ 493, *et seq.*

11. Defendant, Seema Verma, sued in her official capacity only, is the Acting Administrator of the Centers for Medicare and Medicaid Services (the “**Administrator**”).

12. Defendant, Jeff Kahrs, sued in his official capacity only, is the Deputy Regional Administrator for the Center for Medicare and Medicaid Services (“**CMS**”), Region 7 (the “**Regional Administrator**”).

13. Secretary Azar has delegated to the Administrator and Regional Administrator of CMS substantial responsibility for administering the Medicare Act and the federal responsibilities of the Medicaid Act.

14. The Missouri Department of Health and Senior Services (“**MDHSS**”) is the State Agency authorized to perform surveys in clinical laboratories for CMS in Missouri and the MDHSS survey team members are considered agents of CMS.

B. JURISDICTION AND VENUE

15. This is a civil action for declaratory relief, injunction, and issuance of a temporary restraining order pursuant to the Federal Rules of Civil Procedure, including but not limited to F.R.Civ.P. 65, and the general legal and equitable powers of this Court.

16. This action arises under the Public Health Service Act, 42 U.S.C. §§ 263a, *et seq.*, the Clinical Laboratory Improvement Amendments of 1988, 42 C.F.R. §§ 493, *et seq.*, as well as the Fourteenth Amendment to the United States Constitution.

17. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because this action arises under the Constitution and federal statutes and regulations.

Medicare regulations do not require GHC to exhaust all of its administrative remedies prior to seeking judicial review. *See Illinois Council on Long Term Care Inc. v. Shalala*, 143 F.3d 1072, 1076 (7th Cir. 1998), *rev'd on other grounds*, 529 U.S. 1 (2000.)

18. Venue is proper in this Court pursuant to 28 U.S.C. § 1391. GHC's main office is located in Poplar Bluff, Missouri. The two locations that are the subjects of this complaint and the subject surveys occurred at GHC's Poplar Bluff and Springfield locations; both of which are in Missouri; and GHC seeks to enjoin both state and federal actions that will take place in Poplar Bluff and Springfield, Missouri.

C. RELEVANT STATUTORY AND REGULATORY FRAMEWORK

19. Title XVIII of the Social Security Act, 42 U.S.C. § 1395 (1979), sets forth the statutory requirements for participation in the federally funded Medicare program. This program, administered by the Department of Health and Human Services ("HHS") (formerly the Department of Health, Education and Welfare) provides health insurance benefits for aged and disabled persons by making payments directly to the institution or individual providing the health service or care (rather than to the individual beneficiary.) 42 U.S.C. § 1395c and f (1979.) In order to receive payment for services rendered to a Medicare patient, an institution must meet the conditions of participation prescribed by the Social Security Act and accompanying regulations. *See* 42 U.S.C. s 1395 (1979) and 42 CFR s 405.1011 et seq. (1980.)

20. As a requirement to perform testing under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and to bill for services provided to Medicare beneficiaries or Medicaid recipients, GHC must comply with all CLIA requirements, 42 CFR § 493, *et seq.*

21. The federal regulations that implement CLIA are found in 42 C.F.R. Part 493. Those regulations spell out "conditions" and "standards" that a laboratory must meet in order to

obtain and maintain federal certification. 42 C.F.R. § § 493.1, 493.3, 493.5(c.) The “conditions” for CLIA certification are general requirements, and the “standards” are specific sub-parts - or components - of the “conditions.” *See, id.*

22. The Secretary of HHS has delegated his statutory authority to enforce CLIA to CMS, which may inspect a certified laboratory to verify its compliance with applicable federal requirements (or designate an agent, such as a state health agency, to carry out that function.) 42 U.S.C. § 263a(g); 42 C.F.R. §§ 493.1800(b), 493.1771-.1773. If an inspection reveals one or more “condition level deficiencies” - that is, noncompliance with any certification “condition” specified in subparts G through Q of the CLIA regulations - CMS may impose “sanctions” on the laboratory. 42 C.F.R. §§ 493.1804(b)(2), 493.1806(a)-(b), and 498.2 (definitions of “condition level deficiency” and “condition level requirements”).)

23. With one (inapplicable) exception, the revocation of a laboratory's CLIA certificate disqualifies both the laboratory's owner and “operator” from owning or operating any laboratory for at least two years. 42 U.S.C. § 263a(i)(3.)

24. A laboratory may challenge CMS's determination to revoke its CLIA certificate and impose alternative sanctions by requesting a hearing before an Administrative Law Judge (“ALJ”) and, then, by requesting the Departmental Appeals Board at HHS (the “**Board**”) review of any adverse decision by the ALJ. 42 C.F.R. § 493.1844(a)-(b), (f.) Proceedings before the ALJ and the Board are governed by the procedural regulations in 42 C.F.R. Part 498. *Id.* § 493.1844(a)(2)-(3.)

25. Unless CMS has alleged that conditions at the laboratory pose an imminent and serious risk to human health, the filing of an administrative appeal postpones the effective date of a challenged revocation “until after a hearing decision by an Administrative Law Judge is

issued.” *Id.* §§ 493.45(g), 493.1812(b), 493.1844(d)(2); *see also id.* § 493.1840(e)(1) (“CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.”.)

26. Here, CMS made allegations of Immediate Jeopardy and has confirmed that CMS intends to proceed with its imposed sanctions without having considered the information GHC provided that establishes there was no patient safety issue and no Immediate Jeopardy, which would postpone the imposition of CMS sanctions until GHC had the opportunity to refute and disprove the alleged deficiencies at the administrative hearing.

D. GHC AND ITS LABORATORIES

27. GHC is a supplier of laboratory and other diagnostic testing services to healthcare facilities and providers in eleven states through its five laboratory locations. GHC’s main office and laboratory is located in Poplar Bluff, Missouri. GHC also operates Missouri laboratories in Springfield and St. Louis.

28. GHC offers diagnostic testing services (*e.g.*, laboratory and radiology) to approximately 2,500 long-term care facilities (“LTC”) and physician practices across the Midwest and South, including for patients in Arkansas, Illinois, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Oklahoma, Tennessee, and Texas.

29. For its LTC services, GHC provides very basic studies used to diagnose and monitor the status of a wide range of conditions such as COVID-19, diabetes, cancer, heart disease, pneumonia, urinary infections, influenza, asthma, and arthritis. GHC sends specially trained staff to patients’ bedsides several days each week to draw blood samples, and then transport them to the laboratory which processes them and reports the results to the patient’s physician. This is done the “same day” in situations where the patient’s condition has changed or deteriorated and the alternative would be to transfer the patient via ambulance for admission to a hospital for diagnosis

and treatment. Services are also provided 24/7 on an emergency basis when there is a sudden change in the patient's status as an alternative to transporting the patient to a hospital emergency department.

30. GHC's Poplar Bluff laboratory runs approximately 76,000 lab tests per day and 1,600,000 lab tests per month. 44% of all of GHC's tests are performed at GHC Poplar Bluff.

31. Prior to suspending its COVID-19 Testing, GHC's Poplar Bluff laboratory was performing all - 100% - of the company's COVID-19 tests. The Poplar Bluff laboratory also performs 100% of the company's Urinary Tract Infection tests. GHC's Poplar Bluff laboratory was running 2,000 COVID-19 tests for LTC facilities each day and would be able to do so again if it is able to continue operations.

32. GHC's Springfield laboratory runs prothrombin time ("PT") tests for its facility and physician clients. A PT test is used for patients at risk for blood clots or on blood thinning medication to evaluate the individual's ability to form blood clots appropriately. GHC's Springfield laboratory runs 50 PT tests per day and 990 PT tests per month. By dedicating the GHC's Springfield laboratory to PT testing, GHC is able to provide faster PT results to its client facilities, which is a critical diagnostic tool to ensure patients' health.

33. Fifty percent of GHC's facility-clients are located in rural areas without ready access to other laboratory providers who can support their patients.

34. GHC's Poplar Bluff laboratory has been operating as a certified lab since 1981 and GHC's Springfield laboratory has been operating as a certified lab since 2015.

35. Neither GHC's Poplar Bluff laboratory nor GHC's Springfield laboratory have ever had any significant survey deficiencies or action taken against their CLIA certificates. Anytime a deficiency was cited during a survey, GHC implemented corrective action was deemed acceptable

and the laboratory was found to have returned to substantial compliance after submitting documentation and information alleging its compliance. GHC has never had its allegations of compliance rejected and has never had to revise and resubmit allegations of compliance to any regulatory agency before this issue has arisen.

36. Prior to the first survey in the Poplar Bluff survey cycle, the June 23, 2020 Survey, GHC's Poplar Bluff was last surveyed on August 27, 2019. Although five standard-level deficiencies were cited, none of the deficiencies alleged any patient harm and the first allegation of compliance that GHC's Poplar Bluff laboratory submitted was deemed acceptable.

37. Prior to the first survey in the Springfield survey cycle, the June 25, 2020 Survey, GHC's Springfield laboratory was last surveyed on December 9, 2019. Only three standard-level deficiencies were cited, none of the deficiencies alleged any patient harm and the first allegation of compliance that GHC's Springfield laboratory submitted was deemed acceptable.

E. RECENT SURVEY AT GHC'S POPLAR BLUFF LABORATORY

38. On June 23, 2020, an MDHSS survey team conducted a survey at GHC's Poplar Bluff laboratory (the "**June 23 Survey**").

39. Following the June 23 Survey, MDHSS notified GHC that it identified multiple standard-level deficiencies and one condition-level deficiency by letter dated June 24, 2020 (the "**June 24 Notice**"). (See June 24 Notice, attached as **Exhibit 1**.)

40. The June 24 Notice also directed GHC to submit a written Allegation of Compliance ("**AOC**") describing the corrective actions that have been completed to bring the laboratory back into compliance. (Ex. 1.)

41. However, before GHC was able to submit its AOC in response to the June 23 Survey, MDHSS conducted another survey at GHC Poplar Bluff on July 1, 2020 (the “**July 1 Survey**”).)

42. Before it received the results to the July 1 Survey, on July 6, 2020, GHC submitted its AOC to MDHSS outlining the actions the laboratory had taken and was taking to ensure compliance following the June 23 Survey. (See AOC to June 23 Survey, attached as **Exhibit 2**.)

43. The next day, on July 7, 2020, MDHSS notified GHC that it found three standard-level deficiencies and the same condition-level deficiency (the “**July 7 Notice**”). The July 7 Notice also notified GHC that MDHSS determined that the alleged condition-level deficiency posed Immediate Jeopardy to patient health and safety and that MDHSS AOC would be notifying CMS to impose sanctions. (See the July 7 Notice, attached as **Exhibit 3**.)

44. The same day, on July 7, 2020, GHC also received notice from MDHSS that GHC’s Allegation of Compliance to the June 23 Survey was not acceptable.

45. Thereafter, on July 17, 2020, GHC submitted its AOC to the July 1 Survey as well as a Revised AOC to the June 23 Survey. (See AOC to July 1 Survey, attached as **Exhibit 4**; see also Revised AOC to June 23 Survey, attached as **Exhibit 5**.)

46. By letter dated September 1, 2020, CMS notified GHC that both AOC submissions were not acceptable and that it was proposing potential sanctions (the “**September 1 Notice**”). (See the September 1 Notice, attached as **Exhibit 6**.)

47. GHC again revised its AOC documents to both the June 23 and July 1 Surveys and re-submitted the documents to MDHSS for consideration on September 8, 2020. (See Second Revised AOC documents, attached as **Exhibit 7**.)

48. On September 25, 2020, GHC received notice from CMS that the most recent revised AOC submissions were still unacceptable and that CMS would be suspending GHC's CLIA certificate for its Poplar Bluff laboratory effective October 6, 2020 (the "**Poplar Bluff September 25 Notice**"). CMS also advised GHC that CMS would be revoking the certificate in November and imposing a civil money penalty of \$21,410 per day from October 3 through October 6, 2020 as well. (See the September 25 Notice, attached as **Exhibit 8**.)

49. After receiving the Poplar Bluff September 25 Notice, GHC attempted to work with CMS to resolve the suspension issue and provide an acceptable AOC. (See Third Revised AOC, attached as **Exhibit 9**.) CMS refused to consider any further revised AOCs or reconsider the remedies being imposed.

50. Left with no other option, GHC submitted its request for hearing to the HHS Departmental Appeals Board to request a hearing before an Administrative Law Judge to contest the June 25 Survey findings. (See Poplar Bluff's Request for Hearing, attached as **Exhibit 10**.) Although GHC also filed a motion requested an expedited administrative hearing, no hearing will proceed until after the parties' discovery and disclosure deadline in the administrative appeal, which is not until February 11, 2021 at the earliest. (See Poplar Bluff's Motion for Expedited Hearing, attached as **Exhibit 11**; see also Pre-Hearing Order, attached as **Exhibit 12**.)

51. GHC also filed a Complaint for Temporary Restraining Order and for Preliminary and Permanent Injunction with this Court. (See Docket No. 6:20-cv-03313-SRB.)

52. Before GHC could be heard on its Complaint, CMS agreed to rescind all imposed remedies pending validation of compliance. (See the October 5 Springfield Rescission Notice, attached as **Exhibit 13**.) GHC dismissed its Complaint in response to what GHC thought was a showing of good faith by CMS.

51. By that time, GHC had implemented all of its corrective actions in the AOC and believed it had returned to compliance.

52. Thereafter, on October 7, 2020, an MDHSS survey team conducted another survey at GHC's Poplar Bluff laboratory (the "**October 7 Survey**"). Following the October 7 Survey, MDHSS notified GHC that it identified multiple standard-level deficiencies and one condition-level deficiency by letter dated October 15, 2020 (the "**October 15 Poplar Bluff Notice**"). (See October 15 Poplar Bluff Notice, attached as **Exhibit 14.**) The October 15 Poplar Bluff Notice gave GHC until October 26, 2020 to submit an AOC demonstrating that the alleged deficiencies have been corrected. (*Id.*)

53. The deficiencies cited during the October 7 Survey were new and different deficiencies – the prior deficiencies cited during the June 23 and July 1 Surveys were not raised or cited. Instead, the new the Condition Level deficiency alleged that that the laboratory workspace layout did not have a unidirectional workflow to avoid possible contamination. (Ex. 14.)

54. The next day, on October 16, 2020, GHC submitted documentation to CMS confirming that it was suspending all COVID-19 testing at the Poplar Bluff Lab until the laboratory layout and workflow was adjusted to correct the issue in order to resolve and remove the alleged condition-level deficiency. (See October 15, 2020 letter to Ms. Cheryl Dobbe, attached as **Exhibit 15.**)

55. GHC followed up on October 20, 2020 with another letter that provided an update on its efforts and progress to establish the unidirectional workflow and asked that CMS consider the condition-level deficiency abated, or removed. (See October 20, 2020 letter to Ms. Cheryl Dobbe, attached as **Exhibit 16.**)

56. CMS did not respond to either letter.

57. Meanwhile, Poplar Bluff had also been preparing its AOC related to the other deficiencies cited during the October 7 Survey to be submitted on or before October 26, 2020.

58. However, on October 21, 2020, before the AOC was due, CMS notified GHC that it was suspending GHC's CLIA certificate effective October 26, 2020 (the "**October 21 Poplar Bluff Notice**") – the same day the AOC is due. (*See* the October 21 Poplar Bluff Notice, attached as **Exhibit 17**.) Based on the October 21 Poplar Bluff Notice, GHC's AOC cannot and will not be reviewed or considered in any meaningful way before CMS suspends GHC's CLIA certificate.

59. GHC has attempted to work with CMS to resolve this timing issue so that GHC can present its AOC demonstrating compliance. To date, CMS has not responded other than to instruct GHC to contact its attorneys. By CMS' actions, it is clear that CMS intends to proceed with suspension without considering the possibility that GHC corrected the deficiencies and returned to compliance despite its own correspondence that gives GHC that opportunity.

F. RECENT SURVEYS AT GHC'S SPRINGFIELD LABORATORY

53. On June 25, 2020, an MDHSS survey team conducted a survey at GHC's Springfield laboratory (the "**June 25 Survey**").

54. By letter dated June 29, 2020 (the "**June 29 Notice**"), MDHSS notified GHC Springfield that it identified multiple standard-level deficiencies and two condition-level deficiencies during the June 25 Survey. (*See* June 29 Notice, attached as **Exhibit 18**.)

55. The June 29 Notice also alleged that the two alleged condition-level deficiencies posed Immediate Jeopardy to patient health and safety and that MDHSS would be notifying CMS to impose sanctions. (Ex. 18.)

56. Thereafter, on July 11, 2020, GHC Springfield submitted its Allegation of Compliance ("**AOC**") to MDHSS outlining the actions the laboratory had taken and was taking to

ensure compliance following the June 25 Survey. (*See* AOC to June 25 Survey, attached as **Exhibit 19.**)

57. More than a month later, by letter dated August 27, 2020, MDHSS notified GHC Springfield that its Allegations of Compliance pertaining to the June 25 Survey were not acceptable and that it would impose sanctions beginning October 6 (the “August 27 Notice”). (*See* the August 27 Notice, attached as **Exhibit 20.**)

58. Following receipt of the August 27 Notice, GHC Springfield prepared a revised AOC to the June 25 Survey and submitted the revised AOC to CMS on September 4. (*See* Revised AOC to June 25 Survey, attached as **Exhibit 21.**)

59. On September 25, 2020, GHC received notice from CMS that the most recent revised AOC submissions were still unacceptable and that CMS would be suspending GHC’s CLIA certificate for its Springfield laboratory effective October 6, 2020 (the “**Springfield September 25 Notice**”). CMS also advised GHC that CMS would be imposing a civil money penalty of \$21,410 per day from October 3 through October 6, 2020 as well. (*See* the Springfield September 25 Notice, attached as **Exhibit 22.**)

60. After receiving the Springfield September 25 Notice, GHC attempted to work with CMS to resolve the suspension issue and provide an acceptable AOC. (*See* Second Revised Springfield AOC, attached as **Exhibit 23.**) CMS refused to consider any further AOCs or reconsider the remedies being imposed.

61. Left with no other option, GHC submitted its request for hearing to the HHS Departmental Appeals Board to request a hearing before an Administrative Law Judge to contest the June 25 Survey findings. (*See* Springfield’s Request for Hearing, attached as **Exhibit 24.**) Although GHC also filed a motion requested an expedited administrative hearing, no hearing will

proceed until after the parties' discovery and disclosure deadline in the administrative appeal, which is not until February 11, 2021 at the earliest. (See Springfield's Motion for Expedited Hearing, attached as **Exhibit 25**; see also Pre-Hearing Order, attached as **Exhibit 12**.¹) .

62. GHC also filed a Complaint for Temporary Restraining Order and for Preliminary and Permanent Injunction with this Court. (See Docket No. 6:20-cv-03313-SRB.)

63. However, before GHC could be heard on its Complaint, CMS agreed to rescind all imposed remedies pending validation of compliance. (See the October 5 Springfield Rescission Notice, attached as **Exhibit 26**.) GHC dismissed its Complaint in response to what GHC thought was a showing of good faith by CMS.

64. By that time, GHC had implemented all of its corrective actions in the AOC and believed it had returned to compliance.

65. Thereafter, on October 8, 2020, an MDHSS survey team conducted another survey at GHC's Poplar Bluff laboratory (the "**October 8 Survey**"). Following the October 8 Survey, MDHSS notified GHC that it identified multiple standard-level deficiencies and one condition-level deficiency by letter dated October 15, 2020 (the "**October 15 Springfield Notice**"). (See October 15 Springfield Notice, attached as **Exhibit 27**.) The October 15 Springfield Notice gave GHC until October 26, 2020 to submit an AOC demonstrating that the alleged deficiencies have been corrected.

66. Importantly, the deficiencies cited during the October 8 Survey were new and different deficiencies – the deficiencies cited during the June 25 Survey were not raised or cited at

¹ The Poplar Bluff and Springfield administrative appeals were assigned to the same Administrative Law Judge who issued one scheduling order for both cases. GHC filed a motion to consolidate the two appeals which is being heard on October 23, 2020.

the October 8 Survey. Instead, the new Condition Level deficiency alleged that that GHC did not have its Technical Consultant on record, or listed in its paperwork. (Ex. 27.)

67. On October 19, 2020, GHC corrected the issue by preparing and filing the necessary documentation to list the Laboratory Director as the Clinical Consultant and Technical Consultant formally. GHC confirmed this correction to CMS by letter dated October 20, 2020. (*See* the October 20 Letter to Ms. Cheryl Dobbe, attached as **Exhibit 28**.) The letter also provides documentation and information demonstrating its actions to correct the alleged standard-level deficiencies. (*See id.*)

68. GHC did not receive any response from CMS.

69. In the meantime, GHC began to prepare its AOC related to the deficiencies identified during the October 8 Survey for submission on or before October 26, 2020.

70. However, on October 21, 2020, before the AOC was due, CMS notified GHC that it was suspending GHC's CLIA certificate effective October 26, 2020 (the "**October 21 Springfield Notice**") – the same day the AOC is due. (*See* the October 21 Springfield Notice, attached as **Exhibit 29**.) Based on the October 21 Springfield Notice, GHC's AOC cannot and will not be reviewed or considered in any meaningful way before CMS suspends GHC's CLIA certificate.

71. GHC attempted to work with CMS to resolve this timing issue so that GHC can present its AOC demonstrating compliance. To date, CMS has not responded other than to instruct GHC to contact its attorneys. By CMS' actions, it is clear that CMS intends to proceed with suspension without considering the possibility that GHC corrected the deficiencies and returned to compliance despite its own correspondence that gives GHC that opportunity.

G. THE UNWARRANTED IMMEDIATE JEOPARDY ALLEGATIONS AT GHC'S POPLAR BLUFF LABORATORY.

72. During the October 7 Survey at GHC's Poplar Bluff laboratory, CMS alleged Immediate Jeopardy to patient health and safety based on GHC's COVID-19 testing only. Specifically, the October 7 Survey alleged that an immediate jeopardy arising from concerns about whether the lab had properly established a unidirectional workflow to avoid possible contamination. (Ex. 14.) This alleged Immediate Jeopardy was a new allegation that was never previously cited or identified in any prior surveys.

73. Furthermore, GHC denies that a deficiency even exists. The survey findings alleges "Molecular amplification procedures that are not contained in closed systems have a unidirectional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation." The instruments GHC uses for amplification are closed. Furthermore, when GHC consulted with the manufacturer of its COVID-19 testing equipment, the manufacturer confirmed that unidirectional flow is not required for GHC's instruments.

74. However, in an effort to demonstrate its commitment to working with CMS towards compliance and process improvement, GHC immediately suspended its COVID-19 testing and revised its laboratory layout and workflow.

75. As of October 17, GHC redirected and sent all COVID tests from Poplar Bluff to third party labs while it awaits CMS confirmation that the unidirectional workflow has been established. (See COVID Testing Report, attached as **Exhibit 30**.)

76. Regardless of whether Immediate Jeopardy existed, GHC has demonstrated, it has developed and implemented substantial systemic corrective actions at the Poplar Bluff laboratory to address the unidirectional workflow. (Exs. 15, 16.) Despite GHC's attempts to communicate these corrective actions to CMS to demonstrate its return to compliance, CMS has not responded.

77. By not responding, CMS is refusing to rescind the Immediate Jeopardy finding and intends to impose the most severe sanction of CLIA certificate suspension against GHC's Poplar Bluff laboratory without basis. (*See* Exs. 14, 17.)

78. GHC acknowledges the importance of compliance and is willing to implement the corrective actions necessary to give CMS confidence in its Poplar Bluff laboratory operations, but it must remain operational to do so.

79. Suspending the CLIA certificate for the Poplar Bluff laboratory and forcing the lab to close before GHC is able to pursue its administrative appeal is not in the public interest.

H. UNWARRANTED IMMEDIATE JEOPARDY ALLEGATIONS AT GHC'S SPRINGFIELD LABORATORY.

80. During the October 8 Survey at GHC Springfield, CMS alleged Immediate Jeopardy due to a concern that the new Laboratory Director was not aware of her responsibility to also serve as the Technical Consultant.

81. This was easily corrected as the new Laboratory Director formally accepted the position of Technical Consultant and acknowledged the responsibilities of the position almost immediately. (*See* Ex. 28.)

82. GHC provided proof that the cited deficiency – and immediate jeopardy – was corrected by letter dated December 20, 2020. (*See* Ex. 28.)

83. But again, CMS has not responded.

84. By not responding, CMS is refusing to rescind the Immediate Jeopardy finding and intends to impose the most severe sanction of CLIA certificate suspension against GHC's Springfield laboratory without basis. (*See* Exs. 27, 29.)

85. GHC acknowledges the importance of compliance and is willing to implement the corrective actions necessary to give CMS confidence in its Springfield laboratory operations, but it must remain operational to do so.

86. Suspending the CLIA certificate for the Springfield laboratory and forcing the lab to close before GHC is able to pursue its administrative appeal is not in the public interest

I. GHC'S PATIENTS AND CLIENTS WILL FACE IRREPARABLE HARM IF ITS CLIA CERTIFICATES ARE SUSPENDED.

87. If CMS's suspension becomes effective, the harm to both GHC and its patients will be irreparable.

88. GHC's Poplar Bluff laboratory performs approximately 76,000 tests per day. Almost three-quarters, 73%, of GHC's revenue is derived from Poplar Bluff's laboratory services. There are no other laboratories that have the capacity and capability to perform those tests for long-term care facilities and other healthcare providers, especially on short notice. More than 250,000 patients at nearly 2,500 long-term care facilities will be without immediate access to critical lab testing and portable imaging services.

89. Prior to the subject surveys, GHC had been providing COVID-19 testing for approximately 500 nursing homes, their 8,879 resident-patients and 12,740 nursing home employees. Although GHC suspended COVID-19 testing to implement the unidirectional workflow CMS alleges to be required, GHC is prepared to resume COVID-19 testing after having implemented the unidirectional workflow. If GHC's CLIA certificates are suspended, GHC cannot resume its COVID-19 testing services these nursing homes and residents need. Federal regulatory agencies are mandating at least weekly COVID-19 testing for its employees, thus, having a testing laboratory readily available is important to ensure nursing homes are able to ensure adequate staffing.

90. If GHC Springfield's CLIA certificate is suspended and it must cease all operations on October 26, the physicians who rely on GHC to provide timely, routine PT tests to monitor their patient's coagulation treatment will be without a regional lab that has the capacity and capability to provide these critical tests timely.

91. GHC's other laboratories are not equipped, staffed or set up to assume testing that is performed at GHC's Springfield and Poplar Bluff laboratories.

92. Most of GHC's patients reside in rural areas, including skilled nursing facilities and other long-term care facilities, and do not have immediate access to alternative laboratories and/or alternative imaging service providers.

93. Specifically, 31.8% of GHC's clients, which includes long-term care facilities and other healthcare providers have no other laboratory within the area² and it would take months for another provider to implement procedures to provide the testing that GHC provides to those entities. 42% of GHC's clients have alternative laboratories in the area, but these alternative laboratories do not have the capacity (such as equipment, space or personnel) to handle the volume of services that GHC provides. It would take at least a month or more for these alternative laboratories to increase their capacity to serve GHC's clients. Only 26% of GHC's clients have an alternative laboratory in the area with the resources and capacity to provide the laboratory services that GHC currently provides.

94. Even if GHC were able to operate and perform testing, CMS's sanctions also include revoking GHC's Medicare certification, which will render GHC ineligible to receive payment for laboratory services provided to any patient who is covered by Medicare, Medicaid and/or private insurance company that requires Medicare certification as a condition for payment.

² On average, the closest available laboratory serving long-term care facilities is 160 miles away.

This will effectively force GHC to close for financial reasons. All of the tests GHC runs are reimbursable by Medicare. Approximately 65% of GHC's revenue requires Medicare certification.

95. GHC's closure would not only cause GHC and its patients severe and irreparable harm, but closure will also harm the 700 employees of GHC who would lose their livelihoods because the laboratory is unable to operate.

COUNT I
INJUNCTIVE RELIEF

96. The allegations contained in paragraphs 1 through 95 above are incorporated by reference as through fully set forth herein.

97. Pursuant to Rule 65 of the Federal Rules of Civil Procedure, this Court should enter an Order preliminarily enjoining Defendants from suspending and revoking GHC's CLIA Certificate until CMS provides GHC a reasonable opportunity to appeal the alleged deficiencies identified in the subject surveys.

98. GHC disputes that the deficiencies identified in the October 7 and October 8 Surveys placed GHC's patients in Immediate Jeopardy. Nonetheless, GHC resolved the deficiencies and has not yet been able to submit credible Allegations of Compliance demonstrating that both GHC's Springfield and Poplar Bluff laboratories removed the alleged Immediate Jeopardy and returned to substantial compliance with regulatory requirements before the suspension date.

99. GHC has appropriately and timely initiated its administrative appeal rights and requested expedited hearings on the merits of its case. As the matter will not be set for an administrative hearing until mid-February 2021 at the earliest, GHC will not be able to proceed to

hearing prior to the proposed suspension date of October 26, 2020 and the December 21, 2020 suspension date. (*See* Exs. 12, 17, 26, 29.)

100. While GHC is entitled to appeal CMS's characterization of the alleged deficiencies as placing the health and safety of the patients in Immediate Jeopardy as well as the suspension and revocation of GHC's CLIA certificates, the appeals process is entirely meaningless if Defendants impose the suspension and force the laboratories to close before GHC has any opportunity to demonstrate before an administrative law judge that the deficiencies were not warranted and/or that GHC was in substantial compliance prior to the suspension. If this happens, GHC will close and, even if it would have succeeded in its appeal, it will all be for naught.

101. If CMS is permitted to suspend and revoke GHC's CLIA certificate, GHC, its patients, and the community it serves will suffer irreparable and imminent harm. Suspending GHC's CLIA certificate will make it impossible for the laboratory to continue to operate. Because GHC will not be able to perform any laboratory services, GHC will be unable to operate its laboratories and will be forced to close. In addition to the irreparable harm of putting GHC out of business, CMS's extraordinary remedy will cause serious injuries to the potential patients who will be without access to laboratory services during a global pandemic.

102. GHC's closure would not only cause GHC and its patients severe and irreparable harm, but closure will also harm the 700 employees of GHC, who would lose their livelihoods as a result of the suspension and closure of the laboratory.

103. GHC's closure would also cause irreparable harm to the surrounding community. Thus, an injunction preventing the suspension and revocation of GHC's CLIA certificate greatly benefits the public interest, because it would continue to allow the community to access diagnostic laboratory services for elderly adults in their residential long-term care community. An injunction

would also prevent the disruption and stress that would be caused as these rural long-term care residents and facilities will lose access to a laboratory that is capable providing the high volume of laboratory testing long term care facilities need generally, as well as the high volume of testing needed during the COVID-19 pandemic. At the same time, the public interest is not served by an unwarranted and accelerated shut down of a thriving laboratory that provides medically necessary services to some of Missouri's most vulnerable individuals in crisis and in need.

104. GHC does not have an adequate remedy at law, absent an injunction to preserve the status quo pending the opportunity to demonstrate that it has corrected the alleged deficiencies cited in the October 7 and October 8 surveys and returned to substantial compliance, or the resolution of its request for expedited appeal.

105. Injunctive relief is in the public interest. When balancing the harms, the damage to GHC, its patients and the community will be great if suspension proceeds and GHC ultimately prevails, whereas Defendants will not be harmed in any perceptible way and will not incur any damages if the status quo is maintained and CMS ultimately prevails.

106. GHC is likely to prevail on the merits of its review. Moreover, GHC has corrected the alleged deficiencies cited in these surveys prior to the date its Allegation of Compliance is due and prior to the effective date of the suspension.

107. CMS's actions violate the Due Process clause of the Fourteenth Amendment to the United States Constitution and must be set aside upon ultimate judicial review pursuant to 5 U.S.C. § 706.

108. An injunction is necessary and required in this case to maintain the status quo until the issues between the parties can be heard on the merits through exhaustion of GHC's administrative remedies.

109. Based on the foregoing, and pursuant to Rule 65 of the Federal Rules of Civil Procedure, a preliminary injunction should be issued enjoining Defendants from suspending and revoking GHC's CLIA Certificate until the issues between the parties can be heard on the merits through exhaustion of GHC's administrative remedies.

110. The TRO, if entered *ex parte*, should be made to expire at the sooner of 14 days from its entry or at the conclusion of a hearing on GHC's request for a preliminary injunction.

COUNT II

VIOLATION OF EQUAL PROTECTION GUARANTEES OF FOURTEENTH AMENDMENT

111. The allegations contained in paragraphs 1 through 110 above are incorporated by reference as through fully set forth herein.

112. The Fourteenth Amendment to the United States Constitution provides that a state shall not "deny to any person within its jurisdiction the equal protection of the laws."

113. The Missouri Constitution provides similar equal protection guarantees to Missouri citizens.

114. Defendants, at all relevant times, were state actors purporting to act under color of federal and Missouri law.

115. Defendants intentionally singled out for disparate treatment GHC and its providers by excluding them from the Medicare and Medicaid network.

116. Defendants lack adequate justification for its exclusion of GHC and its providers from the Medicare and Medicaid network.

COUNT III

VIOLATION OF DUE PROCESS GUARANTEES OF FOURTEENTH AMENDMENT

117. The allegations contained in paragraphs 1 through 116 above are incorporated by reference as through fully set forth herein.

118. The Fourteenth Amendment to the United States Constitution provides that a state shall not “deny any person of life, liberty, or property, without due process of law.”

119. Defendants, at all relevant times, were state actors purporting to act under color of federal and Missouri law.

120. GHC’s prior contracts with Defendants, which entitled them to reimbursement for services provided to enrollees as members of the Medicare and Medicaid network, represented constitutionally protected property interests with a legitimate claim of entitlement to their continuation.

121. Defendants’ exclusion of GHC from the Medicare and Medicaid network is a deprivation of the aforementioned protected property interests.

122. Defendants’ deprivation of GHC’s constitutionally protected property interests occurred without notice and a hearing before an impartial decision-maker.

123. Defendants’ actions constitute intentional and continuing violations of GHC’s Due Process rights under the Fourteenth Amendment to the United States Constitution.

WHEREFORE, GAMMA HEALTHCARE, INC. prays for the following relief:

(a) That the Court issue a TRO pursuant to Rule 65(c) prohibiting the Defendants from suspending and revoking GHC’s CLIA Certificate (or taking any actions on the basis thereof, such as revoking GHC’s billing privileges or refusing to pay for its services thereunder) until such time as the Court is able to determine whether the preliminary injunction should remain in effect as a permanent injunction pending GHC’s opportunity to exhaust its administrative appeal remedies;

(b) That the Court order Defendants to appear within 14 days to show cause why said TRO should not remain in effect as a preliminary injunction until the issues between the parties can be heard on the merits through exhaustion of GHC's administrative remedies;

(c) That the Court waive the requirement of a security bond;

(d) That the Court set at the earliest possible time a hearing on a preliminary injunction on this cause;

(e) That the Court issue a preliminary injunction:

- i. Prohibiting Defendants from suspending GHC's CLIA Certificate (or taking any actions on the basis thereof, such as revoking Gamma Healthcare, Inc.'s billing privileges or refusing to pay for its services thereunder) unless and until the issues between the parties can be heard on the merits through exhaustion of Gamma Healthcare Inc.'s administrative remedies;
- ii. Prohibiting Defendants from requiring Gamma Healthcare Inc. to provide notice of suspension to its patients unless and until the Gamma Healthcare Inc. has exhausted its appeal process;
- iii. For such other and further relief as this Court deems just and proper.

(f) That the Court issue a declaratory judgment that Defendants' actions violate the equal protection and due process guarantees of the Fourteenth Amendment.

Respectfully submitted,

POLSINELLI PC

/s/ Blake H. Reeves

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Counsel for Plaintiff Gamma Healthcare, Inc.

VERIFICATION

STATE OF MISSOURI)
) SS.
COUNTY OF)

Jerrod Murphy, being duly sworn on oath, states that he/she has read the foregoing Verified Complaint for Temporary Restraining Order, Preliminary and Permanent Injunctive Relief and that the facts set forth therein are true and correct to the best of his/her knowledge and belief, and that he/she is duly authorized to sign this Complaint on behalf of GAMMA Healthcare, Inc.



Jerrod Murphy
President and Chief Executive Officer
GAMMA Healthcare, Inc.

STATE OF MISSOURI)
) SS.
COUNTY OF Butler)

Subscribed and sworn to before me, a notary public, this 23rd day of October, 2020.



Notary Public

My Commission Expires:

July 5, 2021



RHONDA LACK
My Commission Expires
July 5, 2021
Butler County
Commission #13412567